

Claims 18-162

The only rejection remaining is that reissue claims 18-162 violate the recapture rule.

An important aspect in this case is that the independent reissue claims recite providing a composition that includes "albumin protein", where the issued claims recite "serum albumin protein", and method of treatment claims canceled in the original prosecution recited "protein". This history can be summarized as follows:

Claim 21 canceled in original prosecution	Claim 12 issued in Barrows et al. '114	Reissue claim 18
protein	serum albumin protein	albumin protein

As a result, at least for this reason, reissue claim 18 is broader than the claim issued in Barrows et al. '114 but narrower than the claim canceled in the original prosecution.

The rejection is based on the premise that comparing the reissue claim to the claim canceled in prosecution is not necessary to determine recapture:

Applicants and the examiner disagree on the necessity of comparing the reissue claims with the broadest claims canceled during prosecution of the parent application. (Office Action mailed 12/20/99, page 6)

It relies on the following analysis of In re Clement:

[T]he [court's] analysis is limited to the reissue claims, the patent claims, and the subject matter surrendered during prosecution of the parent application. The final analysis does not mention the canceled claims. (Office action, page 6)

Applicants submit that this reasoning is wrong. First, the rejection seriously misreads Clement.

What the court refused to do was limit the comparison to only the broadest canceled claim (emphasis ours):

[Clement] relies on the unsupported assumption that, for purposes of the recapture rule, we should compare the scope of the reissue claims with that of only original claim 1 to determine whether or not the reissue claim is broader in a material way. Clement has chosen original claim 1 as the basis for comparison because, in his view, it does not include limitations enumerated by the board as missing from the reissue claims. In re Clement 131 F.3d 1464, 1471 (Fed. Cir. 1997).

The court instructs that the proper analysis is to consider each successive amendment and cancellation during prosecution (emphasis ours):

[Clement] ignores much of the prosecution history. The prosecution history shows that Clement abandoned the subject matter of claim 42, as it existed before the examiner's amendment dated May 16, 1988, because he allowed the examiner to amend it to obtain allowance and no other evidence suggests that Clement did not intend to abandon it. He also abandoned the subject matter of claim 42, as it existed before his June 29, 1987, amendment, as it existed before his December 23, 1986, amendment, and as it existed in his preliminary amendment. Based on his actions and statements in the prosecution history of the '179 patent and his admission in the history of the '012 application, every time Clement amended his claims, he intentionally omitted or abandoned the claimed subject matter. Id.

And, in fact, the Clement court compared the reissue claim to the canceled claims to determine in what aspects the reissue claim is narrower (emphasis ours):

Comparing reissue claim 49 with claim 42 before the May 1988 and June 1987, amendments... Id. at 1470.

As a result, the court in Clement applied the analysis that the rejection reasons is not necessary.

In this case, there is no pattern of multiple cancellations. The claims were amended only once, after the first office action, and the comparison to the canceled claim is relatively simple. The independent reissue claims are narrower than the canceled method of treatment claims in that the reissue claims recite providing a composition including "albumin protein", where the canceled claim recites "protein".

Fundamentally, without considering the claims canceled during the original prosecution, the rejection utterly confuses any assessment of the scope of subject matter that may have been

surrendered during the original prosecution and completely fails to consider whether the reissue claims are materially narrower than the canceled claims.

For example, in its reference to surrendered subject matter, the rejection looks to the scope of the claim after the amendment, rather than prior to amendment. Consequently, the rejection reasons that because the limitation to the use of serum albumin protein was added during the original prosecution, applicants surrendered subject matter that does not include serum albumin protein:

These limitations [serum albumin protein] were inserted into the claims eventually allowed in the patent by the amendment ... in order to avoid a prior art rejection ... It is impermissible to claim subject matter in a reissue application which was intentionally canceled during prosecution of the patent application in order to obtain the patent (office action mailed 12/20/99, P. 4).

Clearly, this is incorrect. The issue regarding the scope of surrendered subject matter relates to the scope of the canceled claim, i.e., prior to amendment, not to the claim as amended. This principle is stated clearly in In re Clement:

Deliberately canceling or amending a claim in an effort to overcome a reference strongly suggests that the applicant admits that the scope of the claim before the cancellation or amendment is unpatentable, but it is not dispositive because other evidence in the prosecution history may indicate the contrary. In re Clement 131 F. 3d 1464, 1469.

As a result, the conclusion in the rejection that because the claims were amended during the original prosecution to recite serum albumin that subject matter related to "albumin protein" was surrendered, is wrong. It should be recognized that the limitation to "serum albumin protein" is narrower than the canceled scope, i.e. any "protein" in two ways—by reciting "albumin protein" and a "serum" protein. Clearly applicants did not surrender the scope of the reissue claims reciting "albumin protein" by canceling a claim reciting any protein.

In addition, without considering the scope of the claims canceled during the original prosecution, the rejection completely fails to consider whether the reissue claim is narrower than the canceled subject matter in a way that is material, i.e., narrower in a way that is relevant to the

prior art rejection in the original prosecution. This principle is, again, set forth in Clement (emphasis ours):

In both *Mentor* and *Ball*, the relevance of the prior art rejection to the aspects narrowed in the reissue claim was an important factor in our analysis. From the results and reasoning of those cases, the following principles flow: (1) if the reissue claim is as broad as or broader than the canceled or amended claim in all aspects, the recapture rule bars the claim; (2) if it is narrower in all aspects, the recapture rule does not apply, but other rejections are possible; (3) if the reissue claim is as broad as or broader in an aspect germane to a prior art rejection, but narrower in another aspect completely unrelated to the rejection, the recapture rule bars the claim; (b) if the reissue claim is narrower in an aspect germane to prior art rejection, and broader in an aspect unrelated to the rejection, the recapture rule does not bar the claim. *Id.* at 1470.

Here, there can be no serious arguments that the reissue claims are not narrower than the canceled claims and the narrowing limitations are not material. On balance, they make the scope of the reissue claims narrower than they are broader in a manner pertinent to the prior art rejections during original prosecution. *Cf. id.* at 1471.

Moreover, while Clement may be relevant to the mechanics of the recapture rule analysis, the fact situation in Clement simply does not apply to this case. In Clement, the original prosecution included multiple successive rejections in view of various prior art references which gave rise to a series of amendments, cancellations, and arguments that made clear that various aspects individually were surrendered. *Id.* Here, as mentioned above, the claims were amended only once and the prior art was distinguished based on its failure of the art to suggest that the combination of albumin protein and polyoxyethylene crosslinking agent could yield a matrix effective as a tissue sealant.

More instructive to this situation are In re Richman 409 F. 2d 269 (CCPA 1969) and In re Ball 729 F.2d 1429 (Fed. Cir. 1984). In Ball, the claim in the original prosecution recited "at least one" feedline. *Id.* at 1432. It was undisputed that this claim scope was surrendered in view of prior art when the claim was amended to require "a plurality" of feedlines. *Id.* But by reissue Ball corrected the error that the limitation to a plurality of feedlines was unduly narrow:

In support of its reissue application Ball stated that the original patent was partially inoperative because it claimed less than Ball had a right to claim. Ball identified as error the undue limitation of the claims of the original patent to a plurality of feedlines:

[The] unwarranted limited scope of our original patent claims were errors [sic] that arose without any deceptive intention as a result of inadequate and/or ineffective communication with our former patent attorney, *** and/or as a result of an inadequate understanding on our part of the potential effect of recitations in the original patent claim language under United States laws. Id. at 1433.

As a result of the reissue, the claim was broadened to recite a "single feedline assembly". The court considered whether such broadening was estopped by the recapture rule:

Issues

...

[W]hether Ball is estopped from securing, through reissue, claims covering the single feedline feature. Id. at 1434.

The court compared the reissue claim to the claim canceled during the original prosecution. Id. at 1347. In holding no recapture, the court found "a single feedline assembly" to encompass other structure, such that, on balance, the "single feedline assembly" was materially narrower than the surrendered "at least one" feedline:

The signal feed assembly is more limited than the "at least one" feed means limitation of canceled claim 8. Id.

Likewise here, the reissue claims recite albumin protein which makes the reissue claims narrower in scope the claims canceled in the original prosecution.

Applicants can broaden their claims by reissue in ways related to limitations added during prosecution because aspects of the invention may be innocently overlooked.

This is expressly discussed in Application of Richman 409 F. 2d 269, 257 (CCPA 1969):

[We find no authority for] the proposition that a limitation added to a claim in obtaining its allowance cannot be broadened, under present statutory law, by reissue if the limitation turns out to be more restrictive than the prior art required. Certainly one might err without deceptive intention in adding a particular limitation where a less specific limitation regarding the same feature, or an added limitation

relative to another elements, would have been sufficient to render the claims patentable over the prior art.

Here, the reissue claims cover aspects of applicants' discoveries relating to methods of treatment that were innocently not fully appreciated during the original prosecution. For example, the reissue claims recite use of "albumin" protein rather than "serum albumin" protein. It is narrower than the claim breadth canceled during the original prosecution, which recited any "protein." Moreover, the albumin protein feature distinguishes the art for reasons consistent with the arguments in the original prosecution.

In addition, in view of the prosecution history as a whole, applicants clearly did not surrender the subject matter of the method of treatment reissue claims. In considering the "error" requirement, we keep in mind that the reissue statute is "based on fundamental principles of equity and fairness, and should be construed liberally." *In re Weiller*, 790 F. 2d 1576, 1579 (Fed. Cir. 1986). Surely, recapture should not prevent applicants from obtaining by reissue the aspects overlooked in this case.

The other independent reissue claims in this group (claims 52, 84, 119) are also methods of treatment that require providing albumin protein and should not be subject to the recapture rule at least for the reasons discussed above. In addition, the dependent reissue claims, of course, include further features. As a result, these claims avoid recapture issues for still additional reasons but should be allowable at least for the reasons discussed above with respect to the independent claims.

Claims 300-400

The independent claims in this group are claims 300, 333, 364, and 398. These claims include limitations to protein concentration and crosslinking agent concentration and crosslinking agent molecular weight. They do not include limitation to 'serum' albumin, rather they recite "albumin protein", nor do they specify burst strength. These claims are being presented without prejudice and applicants submit, should be allowable at least for the reasons discussed above.

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There can be no issue that these claims are materially narrower than the method of treatment claims that were amended during the original prosecution - they recite the use of "albumin protein", rather than any protein, they include the protein concentration, they include crosslinking agent concentration, they include crosslinking agent molecular weight, and they include curing the composition on tissue to the said composition to the tissue and to provide a substantive cured matrix.

Allowance is requested.

Applicant submits that all of the claims are now in condition for allowance, which action is requested. Filed herewith is a check in payment of the excess claims fees required by the above amendments and Petition for Automatic Extension with the required fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date:

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